No. **10-17636**

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

TRI-VALLEY CARES, MARYLIA KELLEY and JANIS KATE TURNER,
Plaintiffs-Appellants

v.

UNITED STATES DEPARTMENT OF ENERGY, NATIONAL NUCLEAR SECURITY ADMINISTRATION and LAWRENCE LIVERMORE NATIONAL LABORATORY,
Defendants-Appellees

Appealing United States District Court for the Northern District of California Order Denying Summary Judgment

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APPELLANTS' OPENING BRIEF

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Re: *Tri-Valley CAREs v. U.S. DOE*, 10-17636

Dear Ms. Neumann,

As I previously informed you by email, I have been concerned that Tri-Valley CAREs (TVC) will be unable to comply with the February 28, 2011 deadline established by the U.S. Court of Appeals for its Initial Brief, due to the fact that the I and others in my office have been repeatedly out with seasonal illnesses during the past few weeks. Therefore, I have requested and obtained an extension of the briefing schedule pursuant to Local Rule 31-2.2 of the Federal Rules of Appellate Procedure.

As described to me by an official in the clerk's office, the new briefing schedule is as follows:

TVC's Opening Brief: 3/14/11
DOE's Answering Brief: 4/13/11
TVC's Optional Reply Brief: 13 days after DOE's Answering Brief

As requested by the clerk, I will submit a copy of this letter to the Court when I file TVC's Initial Brief.

Sincerely,

/s/
Scott Yundt

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I. JURISDICTIONAL STATEMENT

The district court had jurisdiction over the Appellants' (Tri-Valley CAREs, Marylia Kelley and Janis Kate Turner, hereinafter referred to as "Tri-Valley CAREs") claims under the Administrative Procedure Act ("APA"), 5 U.S.C. §§701-706, 28 U.S.C. §1331 (action arising under federal laws); §1361 (mandamus), and §§2102-2202 (declaratory judgments). This Court has jurisdiction under 28 U.S. C. §1281 because this appeal is from a final judgment entered September 30, 2010 disposing of Tri-Valley CAREs' claims. Excerpt of Record, Volume 1, Tab 3 (hereinafter abbreviated as 1ER3). Tri-Valley CAREs' notice of appeal, filed November 18, 2010, was timely under Federal Rule of Appellate Procedure ("FRAP") 4(a)(1)(a). 1ER1.

II. ISSUES PRESENTED FOR REVIEW

(1) Whether the Appellees (The U.S. Department of Energy, National Nuclear Security Administration and Lawrence Livermore National Laboratory, hereinafter referred to as "DOE") complied with this Court's mandate in *Tri-Valley CAREs v. Dept. of Energy*, 203 Fed. Appx. 105 (9th Cir. 2006) , when it failed to conduct a comprehensive and objective analysis of the human health, safety, and environmental risks associated with an intentional terrorist act occurring at the

Lawrence Livermore National Laboratory ("LLNL") Biosafety Level -3 Facility ("BSL-3"), as required by the National Environmental Policy Act ("NEPA").

(2) Whether the DOE violated NEPA by failing to supplement its Revised Environmental Assessment for the Biosafety Level 3 Facility at LLNL with information regarding incidents in which DOE violated protocols and policies at LLNL's biological facilities and the significant human health, safety and environmental impacts associated with those violations, and thereby deprived decision-makers and the public of a reasonable opportunity to have meaningful input in the decision making process associated with the BSL-3 facility's authorization, construction and operation.

(3) Whether the district court improperly excluded Tri-Valley CAREs' extra record evidence which proves the inadequacy of using a centrifuge accident as a scenario for analyzing an intentional terrorist act in the *Final Revised Environmental Assessment for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California* (January 2008). 2ER1.

III. STATUTES AND REGULATIONS

Relevant statutes and regulations are included in an addendum to this brief.

IV. STATEMENT OF THE CASE

On September 16, 2003, Tri-Valley CAREs brought suit in the U.S. District Court for the Northern District of California, under NEPA, challenging the 2002 *Final Environmental Assessment for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California* ("EA") on numerous grounds, including that it failed to properly analyze the threat of a terrorist attack on the facility and the environmental impacts that such an attack could cause if dangerous pathogens were released. 1ER19:(page)10, 2ER1. On September 10, 2004, the district court granted summary judgment for the DOE and denied summary judgment for Tri-Valley CAREs. *Tri-Valley CAREs v. U.S. Department of Energy*, 2004 U.S. Dist. LEXIS 18777 (N.D. Cal. Sep 10, 2004). 1ER19:10. In so ruling, the court found DOE's EA supported the issuance of a Finding Of No Significant Impact ("FONSI") and did not require a full Environmental Impact Statement ("EIS"). *Id*.

Tri-Valley CAREs appealed the decision to this Court on November 8, 2004. *Id*.

On appeal, this Court found:

> Concerning the DOE's conclusion that consideration of the effects of a terrorist attack is not required in its Environmental Assessment, we recently held to the contrary in San Luis Obispo Mothers for Peace v. Nuclear Regulatory Commission , In Mothers for Peace, we held that an Environmental Assessment that does not consider the possibility of a terrorist attack is inadequate. Similarly here, we remand for the DOE to consider whether the threat of terrorist activity necessitates the preparation of an Environmental Impact Statement. (*citation omitted*).

Tri-Valley CAREs v. Dept. of Energy, 203 Fed. Appx. at 107; Citing *San Luis Obispo Mothers for Peace v. NRC,* 449 F.3d 1016 (9th Cir. 2006), cert. denied, 549 U.S. 1166 (2007); 1ER23.

On remand, the DOE prepared and circulated for public comment the *Draft Revised Environmental Assessment for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California* (December 2007) ("DREA"), which concluded that intentional attacks on the proposed facility posed no potential significant impact and thus, there was no need to prepare an EIS. 2ER2.

Tri-Valley CAREs and others submitted extensive comments on the DREA that, among other things, requested additional discussion of a shipping incident that had occurred at LLNL's biological facilities in 2005 and that was only briefly mentioned in the DREA without many important details. 2ER1:104. When the details of this incident later came to light, Tri-Valley CAREs realized the extent to which it and other members of the

public had been deprived of their right to provide meaningful comments with regard to these incidents. 2ER3. On January 28, 2008, DOE simultaneously released a *Final Revised Environmental Assessment for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California* (January 2008) ("FREA") (2ER1) and a *Revised Finding of No Significant Impact for the Proposed Construction and Operation of a Biosafety Level 3 Facility at Lawrence Livermore National Laboratory, Livermore, California* (January 2008) ("RFONSI"). 2ER4. The BSL-3 Facility began operation on that day as well. 1ER19:11.

On March 10, 2008, Tri-Valley CAREs filed a new Complaint in the district court alleging that DOE had failed to prepare an adequate FREA and RFONSI, illegally failed to prepare an EIS, illegally failed to properly supplement the FREA with important new information regarding the anthrax incident at LLNL's biological facilities, and illegally failed to publically circulate the RFONSI prior to commencing BSL-3 operations. 1ER19. On March 26, 2008, Tri-Valley CAREs filed a *Motion for Preliminary Injunction* to halt, or at least limit, the facility's operation during litigation on the grounds that it was likely to prevail on the merits of these issues and because the balance of hardships weighed in its favor. 1ER2:3. The district

court found that Tri-Valley CAREs was in fact "likely to prevail on the issue as to whether DOE should have supplemented the [F]REA with information regarding two 2005 shipping incidents," but denied the Motion on the grounds that Tri-Valley CAREs failed to show irreparable harm. 1ER20:40, 50. Thus, the parties proceeded to the merits and fully briefed cross motions for summary judgment. 1ER2:10-13; 1ER8-17.

On October 21, 2009, Tri-Valley CAREs filed its *Motion for Summary Judgement*. 1ER14. In its Memorandum of Points and Authorities in Support of the Motion, Tri-Valley CAREs brought to light newly obtained, and previously undisclosed, information that during an inspection of LLNL biological research facilities in August 2005, the U.S. Centers for Disease Control and Prevention ("CDC") discovered that LLNL researchers were engaged in conducting "restricted experiments" to create an antibiotic resistant strain of *Yersinia pestis* (plague) in violation of the CDC regulations. *Id.*, 42 C.F.R. §73, 2ER5:1; 2ER6:4; 2ER7:4.

Despite this information's relevance to the analysis in the DREA and FREA of LLNL's safety, security and ability to comply with applicable laws and regulations, it was never mentioned in either document and the public was not able to reference or analyze this information in its comments. 1ER14:12-13. Tri-Valley CAREs' received the information in a response to

a Freedom of Information Act (FOIA) request the group submitted in 2007. 1ER15:6-7. Finally, in response to litigation for failing to respond to the group's FOIA requests, DOE produced the documents that revealed the CDC inspection, the restricted experiments to modify the plague virus and the incurred violation of the law. These documents were added to the Administrative Record before the district court. 2ER5; 2ER6; 2ER7.

After the parties completed briefing their motions for summary judgment, Tri-Valley CAREs filed a *Motion for Leave to file a Motion to Augment the Administrative Record* with a recently released report from the National Academy of Sciences ("NAS") that critiques the specific accident scenario – a centrifuge accident – that DOE used as a surrogate for an intentional terrorist act in its EA. 1ER6-7.

On September 30, 2010, the district court entered summary judgment for DOE on the grounds that the FREA had sufficiently complied with NEPA. 1ER3-4. The court's decision also denied Tri-Valley CAREs' motion for leave to augment the record. 1ER3:20-21 Tri-Valley CAREs believes that the district court's grant of summary judgment, which this Court reviews *de novo*, failed to correctly apply the provisions of NEPA and excluded admissible evidence submitted by Tri-Valley CAREs. For these reasons and

others discussed below, Tri-Valley CAREs filed a timely Notice of Appeal to this Court on November 18, 2010. 1ER1.

V. STATEMENT OF FACTS

A. Lawrence Livermore National Laboratory, a DOE Facility

LLNL, a DOE nuclear weapons design laboratory (run by the semi-autonomous National Nuclear Security Administration ("NNSA")), lies just outside the boundary of Livermore, California, about 3 miles from Livermore's central business district and approximately 40 miles east of San Francisco. 2ER1:6. The nearest residence is located across the street from LLNL, and about one-half mile from the BSL-3 facility. 2ER1:50. In 2000, there were about 1.3 million people living in Alameda County, in which LLNL is located, and approximately 6.9 million people living within a 50-mile radius of the laboratory. 2ER1:36. LLNL, employs approximately 8,000 individuals. 1ER19:6.

Over the years, LLNL has had recurrent problems with security issues and the proper management and control of dangerous materials including in its bioscience research programs. 2ER1:59-60, 110-114. These incidents, which include an LLNL anthrax shipping incident in September 2005, have resulted in the exposure of individuals to pathogenic material and environmental degradation. *Id.* As demonstrated by the anthrax mailings in

late 2001, which essentially shut down mail service to the federal government, killed five and caused seventeen additional infections, "dramatic human health impacts and economic disruption can result following the release of pathogenic materials." 2ER1:67. In addition, there is an acknowledged security risk associated with select agent research at the LLNL BSL-3 facility. 2ER1:61-67; 2ER8:5-6.

B. The LLNL Biosafety Level-3 Facility

A Biosafety level refers to the degree of virulence of the biological agents contained in a facility and whether there are known inoculations or cures for people exposed to them. 2ER1:71-83. There are four "Biosafety levels;" the higher the level the greater the degree of protection required to protect personnel, the environment and the community from the dangerous pathogens. *Id*. The highest Biosafety level is BSL-4. *Id*.

Biosafety levels have different combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. *Id*. BSL-3 is suitable for "facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route." 2ER1:78. The DOE originally proposed two BSL-3 laboratories, one at LLNL and the other at its Los Alamos National Lab in New Mexico, as part of the Chemical and Biological National Security

Program, an initiative developed in response to the 1997 Defense Against Weapons of Mass Destruction Act, 50 U.S.C. §2301, and designed to engage the NNSA's laboratories in research related to "preparedness" for biological attacks. 2ER1:8. Shortly after Tri-Valley CAREs filed its original suit in the district court, the DOE withdrew its Los Alamos BSL-3 EA in favor of proceeding with a full EIS for that facility, the draft of which is due out later in 2011. 1ER19:16-17.

The NNSA has operated biological laboratories at LLNL with Biosafety Level -1 and Biosafety Level-2. 2ER1:6. The LLNL BSL-3 is the first constructed and operated within a DOE NNSA nuclear weapons facility, collocating advanced biological weapons agents with nuclear bomb-making materials.

The LLNL BSL-3 facility is a prefabricated, one-story building with about 1,500 square feet of floor space that houses three individual BSL-3 laboratories. 2ER1:5, 15. The operational design life of the building is estimated to be at least 30 years. 2ER1:5. The BSL-3 facility has been constructed and all facility-related equipment installed. 2ER1:4.

At the LLNL BSL-3 facility, biological research projects will be conducted "involving indigenous or exotic agents which may cause serious or potentially lethal or debilitating effects on humans, plants, and animal

hosts, . . . potentially impacting human health as well as agriculture, food, and other industries." 2ER1:13. The facility is equipped to perform operations involving small-animal testing of bioagents and biotoxins, in which up to 100 rodents (mice, rats, and guinea pigs) at a time would be exposed to aerosolized pathogenic material. 2ER1:11, 19. In addition, the facility will have the ability to produce biological material (enzymes, deoxyribonucleic acid, ribonucleic acid, prions, viral agents, bacterial agents, fungal agents, parasitic agents, rickettsial agents, etc.), use infectious agents, and may handle genetically modified microorganisms. 2ER1:9, 11, 21.

The LLNL BSL-3 facility is expected to culture life-threatening bioagents including, but not limited to, the "select agents" anthrax, plague, botulism, Valley Fever, Brucellosis, tularemia, and Q Fever. 2ER1:21. "Select agents" are those biological agents and toxins designated by the Secretary of the U.S. Department of Health and Human Services ("HHS") as having "the potential to pose a severe threat to public health and safety." 42 C.F.R. §73.3.

The BSL-3 may house up to 50 liters of pathogenic material and up to 3 liters of cultured microorganisms may be handled in the three discrete laboratories within the facility at any given time. 2ER1:94. This is a

significant amount of material that, if released as the result of an intentional act, could have a catastrophic impact on public health and the environment.

C. The Initial NEPA Process For The LLNL BSL-3 Facility

The NEPA process for the LLNL BSL-3 facility commenced in 2002. 2ER9. DOE issued the Draft Environmental Assessment on July 24, 2002. 2ER10:7. Over 80 extensive comments were provided, including those from Tri-Valley CAREs and residents of 8 different states and the District of Columbia. 2ER1:89. In December 2002, DOE issued the EA and FONSI for the BSL-3 facility, which authorized construction and operation of the facility. 2ER1:4.

Tri-Valley CAREs filed a lawsuit in federal district court in San Francisco challenging, *inter alia*, the adequacy of the EA and FONSI for the LLNL BSL-3 facility. *Id.* On September 10, 2004, the district court found the EA and FONSI to be adequate. *Tri-Valley CAREs*, 203 Fed. Appx. at 107.

As stated, on appeal, this Court affirmed in part and reversed in part, remanding for "DOE to consider whether the threat of terrorist activity necessitates the preparation of an Environmental Impact Statement." 1ER23. As a result of this Court's decision, on December 1, 2006, DOE issued interim guidance on how to address intentional destructive acts in its NEPA

documents. 2ER1:4, 2ER19. This interim guidance stated that applying accident analyses to an analysis of the potential consequences of acts of sabotage or terrorism would only apply if "the accident scenario involve[d] similar physical initiating events or forces," and explains that "accident scenarios may not encompass potential threats posed by intentional destructive acts." 2ER19.

D. The March 2007 Draft Revised Environmental Assessment

In response to this Court's ruling and its own interim guidance, DOE revised the EA for the LLNL BSL-3 facility in March 2007 and made it available for public comment. *Id.*, 2ER2. Comments were submitted by Tri-Valley CAREs in this action regarding the adequacy of the DREA for the facility and the need for the preparation of an EIS. 2ER1:102-136.

DOE drafted a one-page addition to its *Executive Summary* briefing the findings in its newly minted section called *Analysis of Threat of Terrorist Activity,* which added about nine pages of supposedly "new" text to the DREA (compared with the original EA). 2ER2.[1]

[1] There were several other minor additions appearing in the DREA (amounting to less than four pages total) that were not directly responsive to the 9th Circuit's Order, including: a one-page *Forward* describing the lawsuit and the reason for the revisions (2ER2:2); one sentence announcing that additional comments to the document would appear in the final version (2ER2:13); a paragraph updating the *Description* to note that the facility had been constructed (2ER2:13-14); a one-page update on the *Seismology*

DOE summarizes the findings of its nine-page *Analysis of Threat of Terrorist Activity* as follows;

> 1) a successful terrorist attack involving facility damage and loss of containment is not expected to occur due to the extensive layered security programs at the LLNL; in any event, the environmental consequences would be bounded by the effects that would occur during catastrophic events or operational accidents;
> 2) because pathogenic agents are available in nature and other, less secure locations, operation of the LLNL BSL-3 facility would not make pathogenic agents more readily available to an outside terrorist, or increase the likelihood of an attack by an outside terrorist; and
> 3) the theft of pathogenic materials by an insider from any bio research facility could have very serious consequences; this scenario is not expected to occur at LLNL due to human reliability programs, security procedures, and management controls at the Facility.

2ER2:5.

The *Analysis of Threat of Terrorist Activity* can be divided into two parts: 1) DOE's determination of the probability of a terrorist attack on the LLNL BSL-3 and 2) DOE's explanation of why the effects of any intentional act would fall within the range of effects of the previously analyzed accident scenario from the original EA.

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analysis including information from a LLNL Site Seismic Safety Program and its analyses that were released between the original EA and the DREA (2ER:17); one paragraph about the amount of force the facility could withstand in an earthquake (2ER2:20); and, two short and vague paragraphs about a shipping incident (2ER2:26).

The DREA acknowledges that, compared to analyzing threats posed by accidents, a different approach was required for "the probability analysis" of terrorist activity at the BSL-3 laboratory. 2ER2:27. Yet it concludes, without providing any actual empirical information, that the "probability for a successful terrorist act at the BSL-3 would be extremely low." *Id.* DOE based this conclusion on its assertion that "For malevolent acts, probability data is generally unavailable." *Id*.

DOE explained its strategy for dealing with this purported impracticality as: 1) begin with the "assumption that a terrorist attack would occur", and; 2) increase "levels of protective strategies" to "reduce the risk of a successful terrorist attack to an acceptable level," while, 3) simultaneously reducing the attractiveness of the facility to attackers. *Id*. The DREA then summarily concludes that the already existing protective strategies, including background checks for employees, perimeter fencing, surveillance, security forces, and the existence of biological agents in the environment and at other labs, mitigate the risk of a terrorist attack and the attractiveness of the facility to attackers to an "extremely low" probability. 2ER2:27-34.

DOE paid lip service to a *Biological Risk and Threat Assessment for Building 368 BSL-3 Laboratory* (LLNL 2005) developed for the BSL-3 facility and claimed that it examined "the potential vulnerabilities of the

facility and its operations to mitigate risks," however, in the record, DOE withheld all of the text of this document, as classified. DOE also does not refer to the document in any detail, other than to say that it corroborates the assertion that the potential for terrorist activity is limited.[2] 2ER2:30; 2ER11.

The bulk of the nine-page *Analysis of Threat of Terrorist Activity* is devoted to explaining how and why the effects of any intentional act would fall within the already existing accident scenario from the original EA. 2ER2:26-35.

This new section in the DREA briefly mentions three types of threats in that context: (1) facility damage or destruction from direct terrorist attacks that results in loss of containment; (2) the theft and subsequent release of pathogenic material by a terrorist from outside LLNL; and (3) the covert theft and subsequent release of pathogenic material by an insider with access to the facility. *Id.*

Illogically, for each of the three "types of threats," which include a suicidal place crash and an explosive device delivered by vehicle or on foot,

[2] On January 18, 2011 DOE produced a redacted version of its *Biological Risk and Threat Assessment for Building 368 BSL-3 Laboratory* (LLNL 2005) to Tri-Valley CAREs in response to a *Freedom of Information Act* request made on October 11, 2007. 5 U.S.C. §552 et seq. Despite these redactions (which Tri-Valley CAREs is appealing administratively), Tri-Valley CAREs was able to decipher that the document contained significant relevant information that should have been disclosed in the record and in the DREA and FREA. 2ER11.

the DOE determined that the "bounded or outer limits" of any release due to a loss of containment would be exactly the same as the impacts of a release attributable to a centrifuge accident. 2ER2:28. DOE already used this same scenario in the EA to analyze the impacts of an accident or natural catastrophe.[3] *Id*. Thus, DOE enabled itself to use the impacts analysis of this discredited scenario (originally intended for a different site and agency) to fulfill the full range of potential incidents, from a lab worker accident involving an experiment to a plane crash, from an earthquake to intentional internal theft or sabotage to a bombing. No other impact analysis was evaluated in detail and no new impact analysis was completed in response to this Court's Order.

The accident scenario, used as a surrogate for an intentional attack, involves a centrifuge accident involving a one-liter slurry of *Coxiella burnetii*. 2ER2:23. The physical initiating event in this accident scenario is a laboratory worker's failure to insert O-rings or tighten centrifuge caps on six vials of *Coxiella burnetii ("C. burnetii)"* in a free-standing centrifuge. *Id.* The centrifuge is activated and a fraction of the tubes' contents is aerosolized. *Id*. The Army then modeled a plume of *C. burnetii* as it moved

[3] This accident was originally developed by the U.S. Army for NEPA analyses of accidents in its own biological research labs and has since been discredited by the NAS as a faulty scenario to use for NEPA reviews of impacts of intentional acts. *See Infra at VIII.F.2.*

though the lab and into the ventilation system. *Id*. The Army assumes that the lab has one operational HEPA filter that is 95 percent effective. *Id.* The scenario concluded that the chance of public exposure was extremely remote. *Id*. This scenario does not include any examination of the impact or consequences of anyone outside of the lab suffering exposure or contracting an illness. *Id*.

The DOE then concluded that the chances of exposure at LLNL would be even less because, unlike the Army's scenario, the LLNL BSL-3 will filter all room air through two HEPA filter banks, each of which is at least 99.97 percent effective. 2ER1:58. DOE also explained that the Army scenario would have a higher exposure rate because it assumes a close proximity to the public, but LLNL's BSL-3 is one-half mile from the nearest public area (not including the labs approximately 8,000 employees who could be in closer proximity to the facility than members of the public). 2ER2:24-25, 1ER19:6. Finally, DOE claims that, because the Army's scenario assumed lower wind speeds than are prevalent at LLNL, higher wind speeds would decrease airborne concentrations more quickly and reduce the impacts. *Id*.

The DREA acknowledges that the physical initiating events or forces in potential sabotage or terrorist scenarios may include a suicidal plane crash, explosion, fire, damage to one or more of the facility's containment features,

or damage to the facility's autoclaves, which are used to kill or sterilize microorganisms. Yet, DOE failed to analyze a scenario of this sort. 2ER2:15, 28; *See* 2ER21:27-29 (another NEPA analysis of sabotage actions that may result in a loss of containment at another BSL-3).

DOE argued that several factors would limit the consequences of an attack that breaches containment, including; that limited amounts of biological agents would be in use; that when not in use, organisms are stored in locked in freezers.[4] 2ER2:28.

Next, DOE summarily concluded that the heat of a fire resulting from an airplane crash or explosive device of the magnitude necessary to breach containment would kill BSL-3 organisms quickly. *Id*. In its comment on the DREA, and via an expert declarant, Tri-Valley CAREs pointed out that DOE's proposition requires significantly more analysis given that "[d]ecades of work in the U.S., Soviet, and other biological weapons programs demonstrated unequivocally that microbial agents could be effectively disseminated in explosive munitions" (which necessarily involve high temperatures). 1ER22:7.

[4] In response to public comments on this issue, DOE added that if the structure was breached and dispersible biological material was released, the negative pressure in the building would draw air into it and exhaust it through the HEPA filters." 2ER1:98.

The DREA also asserts that any force sufficient to breach containment would also breach containers of bleach, which would then kill the organisms. 2ER2:28.

DOE concludes -- with a sweeping finding similarly lacking in any sort of justifying analysis -- that in the event of a bioagent release, microorganisms would generally be rendered innocuous by exposure to outside conditions, in particular, sunlight and dehydration. *Id*.

The DREA also concludes a lack of impacts on public health from a release based on the assertion that all of the bioagents present in the BSL-3 facility cause diseases for which treatment or inoculation is available. 2ER2:29. DOE also points to vague steps taken to brief local health care providers. *Id*. However, this section fails to mention the experiments at the facility that will involve novel genetically modified bioagents in the BSL-3 or the fact that LLNL was already found to have been violating select agent rules for conducting experiments to create an antibiotic resistant strain of the plague. 2ER5-7.

Finally, DOE briefly asserted that the probability of a successful terrorist attack would be mitigated by the extensive security measures in place at LLNL, specifically the patrolled security fence with badge-identification required for entry and its armed emergency response force. 2ER2:29-30.

DOE also cites the BSL-3's limited access (to CDC registered employees) and motion sensor security system. 2ER2:30. The DREA makes no mention of LLNL's failed security "force on force" tests in 2006, where the protective force's response was found to be erratic and unacceptable, even after nine months of advance notice and preparation. 1ER23:4.

Despite the history of the 2001 anthrax mailing attacks on the Senate and House office buildings in Washington, D.C. and decades of historical biological weapons development and use around the world, no analysis involving these scenario types was completed.

E. The January 2008 Final Revised Environmental Assessment

On January 25, 2008, after evaluating the new and extensive public comments that challenged many of the DREA's controversial findings, the DOE simultaneously issued the FREA, with brief responses to the comments, and an RFONSI for the BSL-3 facility, thereby determining that an EIS was not required. 2ER1:89-136, 1ER4:10. This FREA duplicated the DREA, except for a few administrative updates, three brief substantive updates, and the comments and responses. 2ER1:6, 8, 10, 12-13, 53, 59, 89-136. Just one of these updates addressed the "threat of terrorism," focusing on describing the anthrax shipping incidents of 2005 in more detail. 2ER1:59.

F. Serious Violations Excluded From NEPA Review

DOE failed to disclose relevant details of two serious incidents that came to light during the NEPA process, nor did they provide necessary analysis of the incidents.

i. Anthrax Shipping Incidents

In August-September 2005, while the first lawsuit filed by Tri-Valley CAREs on this matter was pending before this Court, an unauthorized individual gained access to LLNL's biological research facilities and was responsible for two anthrax shipping incidents and multiple exposures. 2ER12. Detailed information concerning these incidents was withheld from the public until over two years later—after this Court had rendered its decision to remand the original EA for a more thorough terrorism analysis. Details came to light only when LLNL was fined by the HHS and the agency placed that information on its website. 2ER13.

The May 11, 2007 DREA included only a brief, and misleading, description of a 2005 shipping incident stating:

> LLNL has never had a biological-material transportation accident (PC 2002). However, in September 2005, LLNL sent shipments of vials containing select agent materials to two offsite laboratories. Upon receipt, it was determined that the inner packaging of these shipments violated DOT packaging requirements and that the labels were missing important information. No illnesses or injuries occurred. The incident was examined and reviewed by the CDC and the DOT. In addition,

> an Incident Analysis Committee was empanelled [sic] by the LLNL to review the incident to determine the root causes, During the review period, all select agent transfers were suspended at LLNL.
>
> At the end of the review, the CDC, DOT and NNSA determined that corrective actions were implemented successfully. Subsequently, LLNL's permit to work with select agents and toxins was renewed by CDC in 2006 for 3 years and transfers were allowed to resume.

2ER2:26.

By characterizing this serious incident as a minor violation of DOT shipping and packaging requirements, DOE deceptively downplayed the significance of the incident. For instance, there was no mention that anthrax was the select agent involved, that the anthrax was packaged by an unauthorized individual, (which is clearly relevant to a potential terrorism scenario) or that LLNL's Responsible Official (the individual designated with the responsibility and authority to ensure compliance with the select agent regulations) failed to ensure compliance and was not even present. 2ER3. These omissions of fact hobbled Tri-Valley CAREs', decision makers' and the general public's ability to comment on the incident's relevance to safety, terrorism, transportation and security, which were the focus of the remand. *Id*.

The full truth of the incident only came out because the HHS Office of Inspector General ("OIG") made the details public in a September 24, 2007

announcement that it was fining the Regents of the University of California, as the manager of LLNL, $450,000 to resolve its liability in connection with the incident. 1ER21:9, 2ER3:1-2. At that time, and not before, the following details regarding the incident were released. LLNL did not release its own statement with these details of the accident until a later date.

The anthrax release occurred during a three-stage shipment of approximately 6,400 anthrax samples from LLNL to laboratories in Florida and Virginia. 2ER12:3. On September 16, 2005, LLNL was notified that two employees and three contract workers at the Florida laboratory were exposed to an unidentified liquid while unpacking the second shipment to that facility. 2ER12:5. This liquid was later determined to be anthrax, which required medical treatment, including being prescribed the wide-spectrum antibiotic Cipro, for the laboratory's employees and contract workers. 2ER12:5-6.

Also, on September 16, 2005, LLNL's Responsible Official received a voicemail message from the laboratory in Virginia stating that its shipment had been packaged "at random." 2ER12:5. On September 22nd, the Virginia laboratory notified both the CDC and LLNL of three inventory discrepancies (extra, missing, and mislabeled samples) and packaging deficiencies related to this shipment. 2ER12:6.

Following the anthrax release, CDC suspended all LLNL transfers of select agents and LLNL issued a full stand-down of all select agent work. 2ER1:59. On November 15, 2005, following an inspection, CDC sent LLNL a letter describing twenty-nine (29) departures from regulatory requirements, including numerous safety and security deficiencies. 2ER6. However, LLNL failed to comply with its own stand-down order and failed to respond to the CDC letter. Approximately two months after research with select agents was suspended, LLNL employees still had access to these materials. 2ER14; 2ER15. In addition, neither LLNL security nor the facility manager were told of the work stand-down and no engineering or administrative controls were put into place to prevent access to select agent materials. 2ER15.

LLNL's internal investigation of this incident, which was completed in December 2005, identified a number of failures. 2ER12. For instance, it was noted that LLNL did not have a "robust, automated inventory system for select agents." 2ER12:9. Furthermore, in numerous instances, individuals deviated from required procedures for handling special agents and/or failed to understand their responsibilities. 2ER12:7-9.

In light of the significance of the anthrax release, and the security and management issues raised by the release, the OIG reviewed the incident. On

January 9, 2007, the OIG wrote a letter to LLNL alleging violations of the select agent regulations, including failure to comply with security and access requirements by providing "an unauthorized individual access to more than 4,000 vials of anthrax" and allowing that individual to package and ship those vials. 2ER16:1. The OIG also alleged that LLNL violated the transfer requirements of the select agent regulations by failing to comply with applicable shipping and packaging laws when transferring a select agent. 2ER16:1-2. Again, LLNL subsequently reached a $450,000 settlement agreement with the OIG to resolve these allegations. 2ER13; 2ER1:54.

Due to this heretofore hidden and now released information's direct relevance to the potential impacts of an insider or outsider threat of terrorism, Tri-Valley CAREs contacted DOE by letter dated October 29, 2007, pointing out a need to prepare a supplement to the DREA, that revised it in accordance with this new information, and re-circulated it for public comment. 2ER3. Tri-Valley CAREs also repeatedly made this point to the district court. 1ER8, 10, 14.

ii. Restricted Experiments

In another incident that reflects on security and management issues and the potential for terrorism and novel deleterious impacts at the LLNL BSL-3, inspectors from CDC discovered on August 30, 2005 that LLNL had been

conducting "restricted experiments" in violation of the select agent regulations promulgated by HHS. 2ER5:1; 2ER6:4; 2ER7:4. One category of "restricted experiments" are those "utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture." 42 C.F.R. § 73.13(b)(1). At LLNL, a researcher had been producing an antibiotic resistant strain of *Yersinia pestis* (plague) in a BSL-2. 2ER6:1-4.

"Restricted experiments" may not be conducted with a "select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary." 42 C.F.R. § 73.13(a). Because LLNL had neither sought nor been granted such approval, CDC required the laboratory to destroy the samples immediately as a condition for LLNL to keep its certificate of registration, authorizing the possession, use, and transfer of select agents and toxins. 2ER7:4. In both the DREA and FREA, DOE failed to disclose that LLNL had conducted "restricted experiments" without the required approval and been reprimanded by the CDC. 2ER1; 2ER2; 2ER7. Failure to disclose this violation in the DREA prevented Tri-Valley CAREs and the public from providing any public comment on its

broad relevance, including: 1) whether a terrorist might find the site attractive due to the presence of genetically modified, antibiotic resistant bioagents; and, 2) whether DOE's assertion that there are inoculations available for the special agents it houses was accurate.

G. HSS Inspection Validates Security Concern

During March and April 2008, after the issuance of the FREA and RFONSI, DOE's Office of Health, Safety and Security ("HSS") inspected safeguards and security and cyber security programs at LLNL. 2ER17:4. The inspection evaluated LLNL in the following protection-related topical areas, among others: personnel security, physical security systems, material control and accountability, protective force, and protection program management. 2ER17:5. HSS gave LLNL's protective force the lowest possible rating, "Significant Weaknesses," due to its poor performance against identified adversary threats, "particularly during force-on-force scenarios and in other types of performance assurance testing." 2ER18:5-6; 2ER8:4. HSS also identified deficiencies in LLNL's physical security systems and protection program management. 2ER17:75-6.

A subsequent report prepared by the U.S. Government Accountability Office ("GAO"), the investigative arm of Congress, noted that LLNL failed to sustain corrective actions implemented in response to the findings of

inspections of security performance at LLNL in June 1999 and April 2002. 2ER18:9.

VI. SUMMARY OF ARGUMENT

In *Tri Valley CAREs,* this Court overturned DOE's decisions that refused to consider the potential environmental impacts of a terrorist attack that would include potentially lethal pathogens, aerosolization of deadly diseases and genetic modification of select agents. This Court remanded the case with the specific order that the DOE augment its NEPA analysis for the subject BSL-3 facility with an analysis of the threat of terrorism and its effects in accordance with the Court's prior decision in *Mothers for Peace,* indicating that a full EIS could be required. 449 F.3d 1016.

On remand, DOE's minimal "revisions" to its NEPA analysis, which found without any cited new empirical study or in-depth analysis that "the threat of a successful terrorist act the LLNL BSL-3 Facility [was] very low," failed to satisfy this Court's Order and the directive of *Mothers for Peace*. *Id*.; 2ER1:61. DOE reached the patently absurd conclusion that the potential environmental effects of an attack on the facility by an intentional actor or actors would be no more significant than those in the centrifuge accident scenario that it had already analyzed. In reaching this conclusion, the agency illogically and illegally left out details regarding two serious incidents that

had recently occurred at its facilities (the anthrax shipping incident and the restricted plague experiment violation), thereby depriving Tri-Valley CAREs and the public of the opportunity to comment on their relevance to the BSL-3's security, the possibility of select agent transportation accidents, the potential impacts of novel, genetically modified bioweapon agents and the potential impacts of a terrorist attack, including by an insider.

In its haste to issue the RFONSI and begin operating the facility, DOE failed to take the "hard look" at the threat of a terrorist attack on the facility and the environmental impacts that may result from such an attack on the facility, thereby violating NEPA, and this Court's specific Order. 42 U.S.C. §4321 *et seq*. 1ER24. It also failed to comply with its statutory duty to supplement and re-circulate its NEPA analysis with the missing relevant information for public comment.

Finally, Tri-Valley CAREs alleges that the district court erred by refusing to allow Tri-Valley CAREs to augment the administrative record for this case with NAS's recent report, *Evaluation of the Health and Safety Risks of the New USAMRIID High Containment Facilities at Fort Detrick, Maryland*. 1ER6-7. This report details the inadequacy of DOE's strategy of using a centrifuge accident scenario as a surrogate for an intentional terrorist attack, and points out that the analysis fails to address numerous relevant

scenarios and factors. *Id*. Because the report demonstrates the DOE's failure to consider relevant factors, it is an appropriate supplement to the Administrative Record now before this Court.

In light of these legal violations, Tri-Valley CAREs seeks an order vacating the FREA and RFONSI for the LLNL BSL-3 facility, and directing DOE to complete an EIS, or, at a bare minimum, reconsider whether an EIS is necessary. Alternatively, the Court should order DOE to prepare a supplement to the FREA, providing Tri-Valley CAREs, decision makers and the public with the opportunity to provide the meaningful public comments that they were previously denied.

VII. STANDARD OF REVIEW

This Court reviews the grant of summary judgment *de novo*, "'view[ing] the case from the same position as the district court' and apply[ing] the same standards." *Brower v. Evans,* 257 F.3d 1058, 1065 (9th Cir. 2001). Hence, this Court must determine, based on the same record, "whether any genuine issue of material fact exists precluding summary judgment and whether the district court correctly applied the substantive laws." *Idaho Sporting Congress, Inc, v. Rittenhouse*, 305 F.3d, 957, 964 (9th Cir. 2002).

The APA, 5 U.S.C. §706(2)(A)-(D), governs review of Tri-Valley CAREs' NEPA claims. *American Disables for Attendant Programs Today v. U.S. Dept. of Housing and Urban Development*, 170 F. 3d 381, 383-84 (3d Cir. 1989). Under the APA, this Court "Shall decide all relevant questions of law, interpret…statutory provisions, [and]… set aside agency action... found to be… arbitrary and capricious, and abuse of discretion, or otherwise not in accordance with the law [or] without observance of procedure required by law." 5 U.S.C. §706(2)(A),(D). In reviewing "primarily legal questions" under the APA, this Court applies a standard of reasonableness. *San Luis Obispo Mothers for Peace,* 449 F.3d at 1028, citing *Alaska Wilderness Recreation and Tourism Ass'n v. Morrison,* 67 F.3d 723, 727 (9th Cir. 1995); *Ka Makani'o Kohala Ohana, Inc. v. Water Supply,* 295 F.3d 955, 959 n.3 (9th Cir. 2002).

VIII. ARGUMENT

Applying the principles of NEPA and the APA in this case, it is apparent that DOE's FREA and RFONSI violates both statutes and must be set aside.

A. The Facts of this Case Distinguish It from the Court's Recent Decision in *Mother's For Peace*

This Court recently rejected the petitioner's request in *San Luis Obispo Mothers for Peace v. NRC* to set aside NRC's Supplemental Environmental

Assessment ("SEA") for expansion of its spent nuclear fuel storage casks at its Diablo Canyon Nuclear Energy Facility due to perceived inadequacies with its analysis of the terrorist threat of the facility. 2011 U.S. App. LEXIS 2896 (9th Cir. Feb. 15, 2011). While both Tri-Valley CAREs and Mothers for Peace obtained orders from this Court requiring federal agencies to revise their NEPA documents with terrorism analyses, significant distinguishing facts should lead this Court to reach a different conclusion in this case.

First, this Court based its finding in *Mothers* on a level of additional analysis done by NRC for its SEA that was not done by the DOE for its FREA. *Id*. at 21-29. On remand, "the SEA review[ed] the NRC's generic analysis of 'plausible threat scenarios,' such as a large aircraft impact and ground assaults, and it f[ound] that current security measures … are adequate." *Id*. at 5. The NRC's 'screening' of threat scenarios "was informed by information gathered through NRC's regular interactions with the law enforcement and intelligence communities." *Id*. at 24.

Here, the DOE did not review any existing '"generic analysis' of plausible threat scenarios," because it, unlike the NRC, does not have one. Rather than complete one, or follow its interim guidance, it chose instead to claim that terrorist scenarios fit into its already previously used Army

centrifuge accident scenario. 2ER19. Nor did DOE allude to gaining information from "regular interactions with law enforcement and intelligence communities" to "screen" the potential threats. The "record [in Mothers] show[ed] that the agency did" *consider* SLOMFP's evidence of the range of alternate scenarios" and NRC "Staff selected 'plausible' threat scenarios based on information gathered from federal agencies and the intelligence community; while the probability of an attack could not be readily quantified, it could be 'qualitatively assessed to be acceptable.'" *Mothers* at 6.

In contrast, in the case now before the Court, DOE made its own broad assertions regarding a very limited range of potential threats on the BSL-3, without using its own guidance or that of the intelligence community, and while it also found the threat of terrorism to be "extremely low," it simultaneously found that "one can even postulate scenarios with catastrophic implications." 2ER1:61, 67.

Second, *Mothers* did not involve the improper withholding of any unclassified information by the agency, but rather involved the Appellants' desire to view information used by the agency in a closed hearing to reach its decision that was determined to be properly closed and classified. Here,

DOE withheld significant unclassified relevant information from the public during the NEPA process.

These important distinctions should lead this Court to a different result in this case.

B. The FREA Fails to Comply with this Court's Order and NEPA

As a result of prior litigation initiated by Tri-Valley CAREs, this Court found,

> Concerning the DOE's conclusion that consideration of the effects of a terrorist attack is not required in its Environmental Assessment, we recently held to the contrary in San Luis Obispo Mothers for Peace v. Nuclear Regulatory Commission , 449 F3d 1016 (9th Cir. 2006). In Mothers for Peace, we held that an Environmental Assessment that does not consider the possibility of a terrorist attack is inadequate. Id. at 1035. Similarly here, we remand for the DOE to consider whether the threat of terrorist activity necessitates the preparation of an Environmental Impact Statement.

Tri-Valley CAREs, 203 Fed. Appx. at 107. 1ER24.

In formulating its initial decision in *Mothers for Peace,* this Court took into consideration "the policy goals of NEPA and the rule of reasonableness that governs its application, and the fact that the possibility of terrorist attack is not so 'remote and highly speculative' as to be beyond NEPA's requirements." 449 F.3d at 1031. The Court continued that, "If the risk of a terrorist attack is not insignificant, then NEPA obligates the NRC to take a

'hard look' at the environmental consequences of that risk." *Id*. at 1032. However, DOE here failed to take the required "hard look" at the environmental impacts that may result from terrorist activity at the LLNL BSL-3 facility, thereby violating this Court's Order, the relevant case law and NEPA.

1. The FREA's Analysis Of Direct Terrorist Attacks Resulting In Loss Of Containment Is Inadequate

DOE failed to comply with this Court's Order because its analysis of the environmental impacts that may result from a malicious act designed to breach containment at the LLNL BSL-3 facility is facially inadequate. As this Court recognized in *San Luis Obispo Mothers for Peace,* Council on Environmental Quality ("CEQ") regulations for the implementation of NEPA require that an EIS must address "events with potentially catastrophic consequences 'even if their probability of occurrence is low, provided that the analysis of impacts is supported by credible scientific evidence, is not based on pure conjecture, and is within the rule of reason.'" *Id*. at 1033 (*quoting* 40 C.F.R. § 1502.22(b)(4)). This Court also said that "[t]he [agency's] actions in other contexts reveal that the agency does not view the risk of terrorist attacks to be insignificant. Precise quantification is therefore beside the point." *Id*. at 1032.

Similarly, in many contexts the DOE reveals its view that the risks of terrorist attack on its facilities are not insignificant.[5] DOE asserts that the likelihood of a catastrophic terror attack on the facility is "extremely low." 2ER1:61. Yet, this Court made it clear in *Mothers for Peace* that "[p]recise quantification [of the risk of terrorist attacks is] besides the point." 449 F.3d at 1032. While remand in this case specifically asked for an analysis of "the risk of terrorism," a finding of a low risk did not relieve DOE of its obligation to take the required "hard look" at the impacts of such attacks when, in other contexts; it acknowledges the fact that terrorist attacks are reasonably foreseeable. 2ER1:63, 68.

However, rather than complete a meaningful analysis of the impacts of a terrorist attack, DOE found that "the consequences of a malicious act designed to breach containment are bounded by the accidents and natural catastrophic events evaluated in the [original EA] because they would result in a similar loss of containment." 2ER1:62. Essentially, the "terrorism analysis" that DOE "prepared" in response to this Court's Order is nothing more than a restatement of the original EA's analysis of the consequences

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[5] Tri-Valley CAREs expert declarant, Peter Stockton, described the great lengths LLNL has gone to trying to protect itself from a terrorist attack. Although those precautions often fail, they are illustrative of the agency view that LLNL *is* at risk and that great precautions must be taken to prevent significant harms that could occur. 1ER23.

that could be expected from an accidental and non-intentional act. 2ER1:106, 125. In violation of NEPA, this conclusory finding is not supported by data in the FREA or the administrative record. See *Great Basin Mine Watch v. Hankins*, 456 F.3d 955, 973 (9th Cir. 2006) (holding that "vague and conclusory statements, without any supporting data, do not constitute a 'hard look' at the environmental consequences of the action as required by NEPA").

According to DOE's own NEPA guidance, it is not appropriate to apply a methodology developed to assess the impact of an accident in the analysis of the potential consequences of acts of sabotage or terrorism where the potential sabotage or terrorist scenarios and the accident scenarios do not "involve similar physical initiating events or forces (e.g., fires, explosions, drops, punctures, aircraft crashes)."[6] 2ER19:2; *see also* 2ER20:4.

Here, the accident scenario applied by DOE is a centrifuge accident involving a one-liter slurry of *Coxiella burnetii*. 2ER1:57. Thus, the physical initiating event in this accident scenario is a laboratory worker's

[6] Tri-Valley CAREs understands agency guidance is not legally binding; however, it is persuasive evidence that DOE's analysis was inadequate when it does not even follow its own guidance. Moreover, it calls into question assertions in the FREA that the "BSL-3 would be operated according to all guidance and requirements established by the CDC and NIH, DOE and LLNL." 2ER1:20. The FREA relies on this assertion to ensure safe operation, yet the agency flagrantly ignores its own guidance in the context of its NEPA analysis. 2ER1:44.

accidental failure to insert O-rings or tighten centrifuge caps properly on six vials of *Coxiella burnetii* in a free-standing centrifuge. *Id.* In contrast, the physical initiating events or forces in potential sabotage or terrorist scenarios may include a suicidal plane crash, explosion, fire, damage to one or more of the facility's containment features, or damage to the facility's autoclaves, which are used to kill or sterilize microorganisms. 2ER1:19, 62, 100.1-100.2, 105-106, 126; 2ER21:27-29 (identifying sabotage actions that may result in a loss of containment). Since the physical initiating events or forces in these scenarios are not similar to the physical initiating event and forces associated with the accident scenario analyzed in the FREA, it was improper for DOE to apply the accident analysis to an analysis of the environmental impacts that may result from a malicious act designed to breach containment at the LLNL BSL-3 facility.

Moreover, according to DOE's guidance, "[e]ach EIS and EA should explicitly consider whether the accident scenarios are truly bounding of intentional destructive acts[,]" which DOE has not done in this case. 2ER19:2. As specified above, DOE claims that "the consequences of a malicious act designed to breach containment are bounded by the accidents and natural catastrophic events evaluated in the [FREA] <u>because they would result in a similar loss of containment</u>." 2ER1:62 (emphasis added).

However, there is no evidence whatsoever in the administrative record that supports this assumption that is at the heart of the so-called terrorism analysis. DOE has misconstrued its own guidance, and the law. The FREA fails to give adequate consideration as to whether the accident scenario in the FREA is truly bounding of a malicious act designed to breach containment at the LLNL BSL-3 facility.

Finally, DOE's claim that the consequences of a terrorist attack resulting in damage or destruction to the LLNL BSL-3 facility and a loss of containment are bounded by the accident scenario discussed above is not credible. According to the DOE guidance regarding intentional and malevolent events,

> In contrast to the randomness of initiators associated with accidents, natural phenomena and other external events, a malevolent, ***intelligent*** initiator can determine where to place explosives or start fires and/or how to use site systems and equipment to deliberately initiate or exacerbate emergency events or conditions. Such premeditated, even suicidal, malevolent events can maximize the impact of a release of hazardous material ranging from use-denial by contamination to serious harm to workers or the public.

1ER11 (emphasis in original). Yet, DOE failed to analyze the potential environmental impacts of a terrorist attack that results in a greater loss of containment than the already mentioned centrifuge accident. *See* 2ER1:57, 60-69. An LLNL worker conducting an act of sabotage or an outside

terrorist could apply human intelligence to the initiating event in a specific and targeted effort to maximize the impact of a release of pathogenic material, beyond that analyzed in the loose caps on vials in the centrifuge scenario. 1ER11.

As a result of these deficiencies, the FREA failed to take a "hard look" at the environmental impacts that may result from a malicious act designed to breach containment. It is clear from the administrative record in this matter that DOE can, and does, distinguish between the consequences of accidental and intentional acts. *See* 2ER21:16-25 (analyzing aerosol release), 2ER21:27-29 (analyzing employee sabotage). And, it is equally clear that DOE failed to draw that distinction in the FREA, despite this Court's clear and express Order to the contrary.

2. The FREA's Analysis Of The Theft And Subsequent Release Of Pathogenic Material By A Terrorist From Outside LLNL Is Inadequate

DOE's analysis of the theft and subsequent release of pathogenic material by a terrorist from outside LLNL is also inadequate. For site-specific actions, like the proposed operation of a BSL-3, the significance of any potential environmental impacts "usually depend[s] upon the effects in the locale rather than in the world as a whole." 40 C.F.R. §1508.27(a). Accordingly, DOE must analyze the significance of the proposed action in

the context of the Livermore locale. *See id.* (the significance of an action must be analyzed in the context of the locality). However, according to the FREA,

> Because a malicious individual could already obtain pathogenic material by other methods under the No-Action ("status quo") Alternative, the presence of pathogenic agents in the proposed, highly secured BSL-3 facility would not pose any new or greater risk to human health or the environment from an outside terrorist or terrorists than already accrues without operation of the BSL-3 facility at LLNL.

2ER1:66. This purported "analysis" plainly neglects to actually analyze the significance of the proposed action in the context of the Livermore locale, and instead relies on the presence of pathogenic material in nature and at other BSL-3 facilities throughout the country to justify its conclusion. 2ER1:65-66, 107, 127-128.[7]

[7] Tri-Valley CAREs' expert declarant, Mark Wheelis, Ph.d., countered the DOE's assertions regarding the "easy availability" of bio agents in nature, saying that because "different strains of a biological agent may have widely varying virulence…[a]nthrax strains isolated from natural veterinary outbreaks cannot be assumed to be highly lethal for humans. Furthermore, it is not a trivial task to isolate such pathogens from nature, although it is within the ability of many Ph.D.-level microbiologists. Thus terrorists might find laboratories to be attractive sources, as they represent a source of known strains with demonstrated human virulence. For instance, the Vollum strain of anthrax was chosen for weaponization by the U.S. offensive biological weapons program in the 1950s because of its lethality (later replaced with a derivative strain, Vollum 1B). The [FR]EA Appendix C at page 9 lists experiments with the Vollum strain as among those planned for the LLNL BSL-3. Therefore, the LLNL BSL-3 might be of particular interest to a terrorist." 1ER22 and 2ER1:93, 133-136.

Here, any discussion of the various inadequacies of the NEPA documentation that DOE prepared must include a discussion of the historical and institutional failures of the agency to provide accurate and objective self-assessment of its security capability. 2ER1:108-109. The recent, aforementioned GAO Report pointed out this failure loud and clear, even citing one DOE official who complained that LLNL's security self-assessment program was "'broken' and missed even the 'low-hanging fruit' of compliance-oriented deficiencies that LLNL must now take actions to correct." 2ER1:15. It goes on to say that, "LLNL's security self-assessment program was not comprehensive and individual assessments of security elements lacked the breadth and depth to provide management with information necessary to make meaningful decisions." 2ER1:14. The GAO Report loudly echoes Tri-Valley CAREs' recognition of DOE's inability to self-assess and failure to analyze its own security at LLNL in relation to a possible terrorist threat and its potential environmental and health impacts.

Additionally, the LLNL BSL-3 facility will house and conduct experiments with a large collection of agents used in bio-weapons, potentially including highly concentrated pathogens, genetically modified microorganisms and unidentified organisms used in bioterrorist attacks, and do so in close proximity to other workers and nearby residents in the City of

Livermore and in the Greater San Francisco Bay Area. 2ER1:6, 11, 21, 40, 93-94, 104. As such, it is clear that the facility poses a new and potentially greater risk to human health and the environment in the Livermore locale, regardless of the availability of some pathogenic materials in other locations. 2ER1:107. Because the FREA failed to adequately analyze this threat, DOE is in violation of NEPA. See *Anderson v. Evans*, 314 F.3d 1006, 1021 (9th Cir. 2002) (holding that an EIS was required because the EA did not adequately address local impacts).

3. The FREA's Analysis Of The Covert Theft And Subsequent Release Of Pathogenic Material By An LLNL Insider Is Inadequate

DOE failed to take a "hard look" at the environmental impacts that may result from the covert theft and subsequent release of pathogenic material by an insider with access to the LLNL BSL-3 facility. According to the FREA, "dramatic human health impacts and economic disruption can result following the release of pathogenic materials[,]" yet DOE failed to analyze any scenarios involving the covert theft and subsequent release of pathogenic material by an LLNL insider. 2ER1:66-67, 107, 128. DOE entirely skipped any analysis of several types of potential sabotage actions, which may include damage to one or more of the LLNL BSL-3 facility's containment features, damage to the facility's containment suite autoclaves,

deliberate release of an infected animal, and deliberate self-infection with the intent to spread the pathogenic material within the environment. 2ER1:60-69.

However, two such scenarios were analyzed in the *Final Programmatic Environmental Impact Statement for the U.S. Army's Biological Defense Research Program* ("BDRP FPEIS"), which is the NEPA analysis "considered most relevant to the Proposed Action[,]" according to the FREA. 2ER21:30-34; 2ER1:55. Such analyses serve the purpose of NEPA, which is "to require disclosure of relevant environmental considerations that were given a 'hard look' by the agency, and thereby to permit informed public comment on proposed action and any choices or alternatives that might be pursued with less environmental harm." *Lands Council v. Powell*, 379 F.3d 738, 745 (9th Cir. 2004).

The FREA includes the same 2 page analysis, *Covert Theft and Subsequent Release of a Pathogenic Material by an Insider with Access to the Facility*, as the DREA, one page of which is spent describing the steps that would be necessary for an insider to successfully carry out a terrorist act at the BSL-3 similar to the 2001 Anthrax Mailing Attack on the U.S. House and Senate office buildings. 2ER2:32-33; 2ER1:66-67, 128. Despite the fact that the alleged perpetrator of the 2001 Anthrax attacks accomplished all of

these steps successfully, this information is provided ostensibly to convince the reader of the difficulty and low probability of such an event.

Then, a scant two paragraphs describe the *Impacts of a Theft and Subsequent Release of a Pathogenic Material* in which DOE acknowledges that "[a]s shown in 2001, dramatic human health impacts and economic disruption can result following the release of pathogenic materials…One could assume that tens of people could be infected and a few unsuspecting or untreated people might die…Taken to extremes, one can even postulate scenarios with catastrophic implications." Id. These vague and conclusory statements regarding the environmental impacts that may result from such a release do not satisfy the "hard look" required by NEPA. Under NEPA, an agency "must put forth a 'convincing statement of reasons' that explain why the project will impact the environment no more than insignificantly." *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 402 F.3d 846, 864 (9th Cir. 2005).

Here, DOE's purported analysis contains no actual empirical analysis or study about the possible environmental impacts of the covert theft and subsequent release of pathogenic material by a LLNL insider. 2ER1:66. In fact, its minimal statements appear to conclude that the potential impacts are "dramatic" and "possibly catastrophic," which is precisely the kind of

finding in an EA that would support completion of an EIS to determine just how significant an impact to the environment this scenario presents. *Id*. Additionally, an EIS would require analysis of mitigation measures in accordance with this finding.[8] Accordingly, DOE is in violation of NEPA. See *Great Basin Mine Watch*, 456 F.3d at 973; *Ocean Advocates*, 402 F.3d at 864 (an agency "cannot avoid preparing an EIS by making conclusory assertions that an activity will have only an insignificant impact on the environment").

4. The FREA Failed To Analyze Other Credible Release Scenarios

Finally, the FREA failed to analyze the environmental impacts that may result from a release of biotoxins, viruses, or genetically modified organisms following a terrorist attack, even though each may be present at the facility. 2ER1:21, 84-85, 104, 133-136. In the BDRP FPEIS, the U.S. Army separately analyzed releases of bioagents, biotoxins, and viruses, and

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[8]Council on Environmental Quality, "Forty Most Asked Questions Concerning CEQ's National Environmental Policy Act Regulations," 46 Fed. Reg. 18,026 (Mar. 23, 1981), Question 19a. Mitigation Measures. What is the scope of mitigation measures that must be discussed? A. The mitigation measures discussed in an EIS must cover the range of impacts of the proposal. ... Mitigation measures must be considered even for impacts that by themselves would not be considered "significant." Once the proposal itself is considered as a whole to have significant effects, all of its specific effects on the environment (whether or not "significant") must be considered, and mitigation measures must be developed where it is feasible to do so.

explained that its analyses "for containment laboratories must be considered in terms of physical containment for both toxins and biological organisms." 2ER21:4-16 (emphasis added); *see also* 2ER22:12-18 (analyzing a biotoxin release).

Although the FREA briefly discusses an accident scenario from another NEPA document involving the release of botulinum, a biotoxin, that analysis cannot form the basis for DOE's decision here, since it is based on the specific features and location of that other facility and the quantities and varieties of biotoxins that will be contained therein. *See* 2ER1:55, 87; 2ER22:7-18; *see also* 2ER21:13-14. The FREA contains no analysis of a release of viruses or genetically modified organisms.[9] 2ER1:104, 133-136.

C. DOE Failed To Sufficiently Inform the Public and Ensure Public Participation

"[T]he comprehensive 'hard look' mandated by Congress and required by [NEPA] must be timely, and it must be taken objectively and in good faith, not as an exercise in form over substance, and not as a subterfuge designed to rationalize a decision already made." *Metcalf v. Daley*, 214 F.3d

[9] Although DOE claims that the rickettsial microorganism *Coxiella burnetii* is "considered representative" of all types of BSL-3 microorganisms, including viruses, for the purpose of analyzing the consequences of an accidental release, 2ER1:53, this statement is unsupported and there is contrary evidence in the record. *See, e.g.,* 2ER21:14-16 (separately analyzing releases of *Coxiella burnetii* and the Rift Valley Fever virus).

1135, 1142 (9th Cir. 2000) (emphasis added); *see also Morongo Band of Mission Indians v. Federal Aviation Administration*, 161 F.3d 569, 575 (9th Cir. 1998). In Mothers for Peace, this Court stated:

> The application of NEPA's requirements… is to be considered in light of the two purposes of the statute: first, ensuring that the agency will have and will consider detailed information concerning significant environmental impacts; and, second, ensuring that the public can both contribute to that body of information [via comments] and can access the information that is made public.

449 F.3d at 1034, Citing *Dep't of Transportation v. Public Citizen*, 541 U.S. at 752, 768 (2004).

Here, DOE failed to disclose important details about the LLNL anthrax release in the DREA, thereby denying public access to the directly relevant details of the incident and prevented public comment regarding the relevant incident.[10] *Compare* 2ER6; 2ER16; 2ER12 *with* 2ER2:57. Samuel Brinker, the NEPA Document Manager for the LLNL BSL-3 facility, was notified of the incident on September 23, 2005, LLNL's internal investigation was complete in December 2005, and the HHS OIG notified LLNL of its potential violations of the select agent regulations in January 2007. 2ER16;

[10] In addition, the administrative record initially filed with the Court by DOE, which was certified as being a "true, correct and complete copy of the administrative record[,]" did not include any documents regarding the anthrax release. *See* 1ER2; 1ER25. Thus, DOE withheld critical and relevant information not only from the public, but also from both this Court and the district court.

2ER25; 2ER12; 2ER24:1; 1ER17. Nonetheless, the March 2007 DREA entirely failed to disclose that anthrax was involved in the incident and that the material had been packaged by an unauthorized individual, among other omissions. *Compare* 2ER16:1 *with* 2ER2:26; 2ER1:104.

Although Tri-Valley CAREs raised the issue of the violation of select agent transfer regulations in its comments to the DREA, the group's ability to comment on the significance of the issues (including that it was perpetrated by an unauthorized individual without a Responsible Official present, that the select agent involved was anthrax or that multiple individuals were exposed upon opening the shipments) was necessarily hamstrung by DOE's deliberate withholding of critical and relevant information pertaining to the incident.

Presumably in response to Tri-Valley CAREs' comments, DOE provided more information on the release in the January 2008 FREA after the opportunity for public review and comment had closed. However, even the FREA failed to disclose important details regarding the incident. *Compare* 2ER6; 2ER16; 2ER12 *with* 2ER1:59-60. For instance, NNSA failed to describe LLNL's numerous regulatory violations, including those involving the laboratory's security plan, Biosafety plan, incident response plan, safety

and biosecurity training, and recordkeeping, among others. *Compare* 2ER6:1-4 *with* 2ER1:59-60.

Moreover, the FREA was not made available to public officials and the public before the BSL-3 facility became operational, in violation of NEPA. *See* 40 C.F.R. § 1500.1(b) ("NEPA procedures must insure that environmental information is available to public officials and citizens before decisions are made and before actions are taken. The information must be of high quality. Accurate scientific analysis, expert agency comments, and public scrutiny are essential to implementing NEPA."); *Bering Strait Citizens for Responsible Res. Dev. v. United States Army Corps of Eng'rs*, 524 F.3d 938, 953 (9th Cir. 2008) ("An agency, when preparing an EA, must provide the public with sufficient environmental information, considered in the totality of circumstances, to permit members of the public to weigh in with their views and thus inform the agency decision-making process").

In briefing and declarations in the district court, DOE attempted to recast its disclosure of the 2005 anthrax shipping incident as one that "included sufficient environmental information" because the incident was a single transportation incident, in which nobody was injured and there was no public release" and it "simply does not alter the potential impacts of the proposed facility." 1ER12:4; 1ER17. However, the incident was actually

two separate shipments of over 4000 vials of anthrax in which 5 people were potentially exposed. Moreover, it exposes significant weaknesses in LLNL's security protocols that go to the heart of the risks associated with the operation of the Livermore BSL-3 facility.[11]

Second, DOE entirely failed to disclose, in both the DREA and the FREA, that LLNL had been conducting "restricted experiments," in violation of the select agent regulations. *Compare* 2ER5:1; 2ER6:1-4; 2ER7:4 *with* 2ER1. In August 2005, inspectors from CDC discovered that an LLNL researcher had been producing an antibiotic resistant strain of *Yersinia pestis* (plague). 2ER6:1-4. As noted above, because LLNL had neither sought nor been granted approval to conduct this experiment, CDC required the laboratory to destroy the samples immediately, in order for LLNL to keep its certificate of registration authorizing the possession, use, and transfer of select agents and toxins. 2ER7:4. The illegal experiments

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[11] DOE's assertion that nobody was injured by the anthrax release is insensitive to the five individuals who suffered exposure to anthrax and were forced to take Cipro. In fact, a class action was filed against Bayer AG on behalf of postal workers who allege that they suffered serious adverse effects from taking Cipro, in the aftermath of the anthrax attacks in 2001. The adverse effects included; tendon rupture, seizures, intestinal problems, tendonitis, anxiety, insomnia, muscle aches, depression, miniscal tears. *Cipro Antitrust Litig. v. Bayer Ag,* 2008 U.S. App. LEXIS 27711 (Fed. Cir. Dec. 23, 2008).

were conducted in 2005, while Tri-Valley CAREs' first case on this matter was before this Court and before preparation of the DREA and FREA. The violations were not ever made public by DOE. It was only through a Tri-Valley CAREs FOIA request and litigation that the violation became apparent. 1ER15. By that time, the RFONSI had been issued and the facility was operating.

Only if a NEPA document is "forthcoming can the public be appropriately informed and have any confidence that the decision-makers have in fact considered the relevant factors and not merely swept difficult problems under the rug." *Sierra Club v. United States Army Corps of Engineers*, 701 F.2d 1011, 1034 (2d Cir. 1983).

Because the FREA is both incomplete and misleading, and was not circulated for comment, DOE must further revise the document and make it available to public officials and citizens for comment. See *Animal Defense Council v. Hodel*, 840 F.2d 1432, 1439 (9th Cir. 1988) (citations and quotation omitted) ("Where the information in the initial EIS was so incomplete or misleading that the decision-maker and the public could not make an informed comparison of the alternatives, revision of an EIS may be necessary to provide a reasonable, good faith, and objective presentation of the subjects required by NEPA."); *NRDC v. United States Forest Serv.*, 421

F.3d 797, 811-12 (9th Cir. 2005) (holding that misleading economic information "was sufficiently significant that it subverted NEPA's purpose of providing decision makers and the public with an accurate assessment of the information relevant to evaluate" the agency's plan).

The details of these significant incidents were relevant to DOE's capacity to protect against intentional terrorist attacks and to implement the security protocols upon which DOE's FREA and RFONSI are based. 2ER6; 2ER16; 2ER12; 2ER2:26. As the district court stated in its *Order Denying Preliminary Injunction*, DOE's "contention that the information was not 'significant' under the NEPA is belied by the very fact the DOE felt compelled to withhold this information until *after* the close of the public comment period and until *after* the termination of the prior litigation." 1ER20:40 (emphasis in original). The court added that "DOE appears to focus too much on the outcomes of the incident, i.e. that nobody took ill or died, rather than on the public's right and need to know in order to make informed decisions and to have meaningful input into government affairs. Further, this information is clearly significant, as it speaks to the 'intensity' or severity of the BSL-3 facility's impact." *Id*. at fn. 29.

Due to this lack of disclosure, the public was unlawfully denied a reasonable opportunity to have meaningful input in the decision-making

process, prior to DOE issuing the FREA. *See* 40 C.F.R. §1500.1(b).[12] In determining whether an EIS fosters informed decision-making and public participation, a reviewing court must determine if its "form, content and preparation foster[ed] both informed decision-making and informed public participation." *California v. Block,* 690 F.2d 753, 761 (9th Cir. Cal. 1982).

D. Failure To Supplement The FREA Violated NEPA

Federal agencies have "a continuing duty to gather and evaluate new information relevant to the environmental impact of [the agencies'] actions." *Warm Springs Dam Task Force v. Gribble*, 621 F.2d at 1024 (9th Cir. 1980) (citing 42 U.S.C. §4332(2)(A-B)). Pursuant to CEQ's regulations, agencies shall prepare supplements to either draft or final EISs if "[t]here are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts." 40 C.F.R. §1509(c)(1)(ii).

The Supreme Court has interpreted NEPA, in light of this regulation, as requiring an agency to take a "hard look" at new circumstances and information to determine whether supplementation may be required. *Norton*

[12] NEPA procedures must insure that environmental information is available to public officials and citizens before decisions are made and before actions are taken. The information must be of high quality. Accurate scientific analysis, expert agency comments, and public scrutiny are essential to implementing NEPA. 40 C.F.R. §1500.1(b).

v. S. Utah Wilderness Alliance, 542 U.S. 55, 72-73 (9th Cir. 2004) (citing *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 378-85(1989)). Although the instant action concerns supplementation of an EA, the standard for supplementing an EA is the same as for an EIS. *Idaho Sporting Congress, Inc.*, 222 F.3d at 566 n.2. Under NEPA, supplementation is required only if there remains major Federal action to occur. *Norton*, 542 U.S. at 73. Here, the FREA encompasses both the construction and operation of the LLNL BLS-3 facility, so there remains major Federal action to occur; namely, the continued operation of the facility. 2ER1.

DOE failed to include, disclose and analyze numerous relevant pieces of new information that came to light during and after the NEPA process. Each failure constituted a violation of NEPA. First, by failing to prepare a supplement to the FREA to analyze the LLNL anthrax release, DOE violated NEPA. DOE also failed to prepare a supplement to the FREA to analyze the "restricted experiments" that CDC discovered at LLNL or the results of the HSS inspection in March and April 2008 in violation of NEPA. As noted, HSS gave LLNL's protective force, which is responsible for responding to intrusion or access control alarms, the lowest possible rating, "Significant Weaknesses." 2ER18:5-6; 2ER8:4-6. HSS also identified deficiencies in LLNL's physical security systems and protection program management,

both of which bear upon the environmental impacts that may result from operation of the facility. 2ER18:5-6.

The aforementioned GAO report, noting that LLNL failed to sustain corrective actions implemented in response to the findings of earlier HSS inspections, lends further support to the need for supplementation here. 2ER18:9. DOE's apparent practice of ignoring new relevant information in its NEPA review precludes the "hard look" analysis required by NEPA, and deprives the public of the opportunity for meaningful participation and contribution.

E. DOE Must Prepare A Comprehensive EIS

This Court examines an "EA with two purposes in mind: to determine whether it has adequately considered and elaborated the possible consequences of the proposed agency action when concluding that it will have no significant impact on the environment, and whether its determination that no EIS is required is a reasonable conclusion." *Ctr. for Biological Diversity v. NHTSA*, 538 F.3d 1172, 1215 (9th Cir. 2008). DOE has neither adequately considered or elaborated on the possible consequences of a terrorist attack, concludes that a terrorist attack scenario could have potentially "dramatic" and "possibly catastrophic," impacts, and did no additional analysis of those "dramatic" and "catastrophic

implications." 2ER1:67. Thus, its RFONSI determining that no EIS was required was not a reasonable conclusion.

The CEQ has set forth a series of factors agencies must consider in determining whether an action may "significantly" impact the environment, thereby requiring an EIS. *See* 40 C.F.R. §1508.27. These include (a) "[t]he degree to which the proposed action affects public health or safety[;]" (b) "[t]he degree to which the effects on the quality of the human environment are likely to be highly controversial[;]" and (c) "[t]he degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks." *Id.* §1508.27(b), *also,* 2ER1:103, 123-124, 129.

If substantial questions are raised as to whether a project may cause significant degradation of some human environmental factor, an EIS must be prepared. *Klamath Siskiyou Wildlands Ctr. v. Boody*, 468 F.3d 549, 562 (9th Cir. 2006). Under this standard, a party need not show that significant effects will in fact occur; merely raising substantial questions whether a project may have a significant effect is sufficient to require the preparation of an EIS. *Klamath Siskiyou Wildlands Ctr.*, 468 F.3d at 562. Here, each of the CEQ "significance" factors listed above requires the preparation of an EIS.

F. The District Court Erred by Denying Tri-Valley CAREs' Motion for Leave to Augment the Record with a Relevant Study

A report from NAS, entitled *Evaluation of the Health and Safety Risks of the New USAMRIID High Containment Facilities at Fort Detrick, Maryland,* ("NAS Report") was released while the parties' cross-motions for summary judgment were pending before the district court. Tri-Valley CAREs filed a Motion for Leave to Augment the Administrative Record with the NAS Report because of its clear and critical relevance to this case. This report critiques the use of the exact accident scenario relied upon by the DOE in this case to reach the conclusion that a terrorist attack on the LLNL BSL-3 would not result in a significant impact to the environment. The NAS Report points to the inadequacy of using the accident scenario as a surrogate for an intentional terrorist act and highlights multiple ways in which the analysis fails to address relevant scenarios and factors. Because the report demonstrates the agency's failure to consider relevant factors, it is an appropriate supplement to the Administrative Record now before the Court.

1. Under the Legal Standards Governing Supplementing an Administrative Record Under the APA, the District Court Should have Allowed Tri-Valley CAREs to Augment the Record with the NAS Report

This Court has recognized four exceptions to the general rule that judicial review of an agency decision under the APA is limited to materials

contained within the agency's administrative record. These exceptions are (1) to determine whether the agency has considered all relevant factors and has explained its decision; (2) when the agency has relied upon documents or materials not included in the recorded; (3) when necessary to explain technical terms or complex matters; and (4) when plaintiffs make a showing of agency bad faith. *Southwest Center for Biological Diversity v. United States Forest Service*, 100 F.3d 1443, 1450 (9th Cir. 1996).

In *Asarco, Inc. v. EPA*, the Ninth Circuit held that "[i]t is both unrealistic and unwise to 'straight-jacket' the reviewing court with the administrative record. 616 F.2d 1153, 1160 (9th Cir. 1980). It will often be impossible, especially when highly technical matters are involved, for the Court to determine whether the agency took into consideration all relevant factors unless it looks outside the record to determine what matters the agency should have considered but did not. The Court cannot adequately discharge its duty to engage in a 'substantial inquiry' if it is required to take the agency's word that it considered all relevant matters." *Id*.

Consequently, this Court may consider extra-record evidence in order to "ascertain whether the agency considered all the relevant factors or fully explicated its course of conduct or grounds of decision." *Id*. See also *Public Power Co. v. Johnson*, 674 F.2d 791, 793 (9th Cir. 1982) ("The broadest

exception to the general rule that review is to be restricted to the record certified by the agency is one which permits expansion of the record when necessary to explain agency action"); and, *Animal Defense Council*, 840 F.2d at 1436 (judicial review may be extended beyond the agency's record if necessary to explain the agency's decisions).

Thus, in making the determination of whether the DOE considered all relevant factors, this Court may consider extra-record information submitted by Tri-Valley CAREs. *National Audubon Society v. U.S. Forest Service*, 46 F.3d 1437, 1447-48 (9th Cir. 1993) (holding that the district court's use of an affidavit submitted by plaintiff's expert who reviewed the administrative record and conducted his own field review of the timber sales in question was proper)*; County of Suffolk v. Secretary of Interior,* 562 F.2d 1368, 1385-86 (2d Cir. 1977) (holding that the "district court properly admitted the testimony of [plaintiff's expert] and the data on which it was based").

2. The NAS Report Entitled 'Evaluation of the Health and Safety Risks of the New USAMRIID High Containment Facilities at Fort Detrick, Maryland' has Significant Bearing on Whether DOE Considered All Relevant Factors and Explained Its Decision

The FREA based its analysis of the threat of a terrorist act on a single 'Laboratory Release Accident Scenario' – the centrifuge accident discussed above -- as a catch-all scenario for any type of attack or accident that could

occur at the facility. 2ER1:61-69. In its justification for using this same catch-all release scenario DOE asserts that the "scenario is also very similar to the BSL-3 accident analyzed in the recently published *Final Environmental Impact Statement for the Construction and Operation of the new USAMRIID Facilities at Fort Detrick, MD* (USAMRMC 2006)." 2ER1:54. This assertion is correct. The scenarios in the two NEPA documents are almost exactly the same. Both involved simulation of biological aerosol releases of Coxiella burnetii into the surrounding environment from an exhaust stack after vials in a centrifuge leaked. Both conclude that ground concentrations would be insignificant and would not pose a hazard to the nearby community. 2ER1:56. The FREA in this case used this finding to support its RFONSI.

NAS evaluated this scenario in the USAMRIID EIS and found the following problems (each and every one of which also apply to the LLNL BSL-3 FREA);

> [T]he committee was unable to verify th[e] prediction [that the ground concentrations would be insignificant and would not pose a health hazard to the community], because the modeling performed in support of the scenarios was not transparent, could not be reproduced, and was incomplete… The committee attempted to verify the calculations using common alternative models. The committee's calculations indicated the potential for

significantly higher doses of infectious agents following puff releases than was described in the EIS.

Other problems with the maximum credible event (MCE) scenarios were the use of inappropriate scenarios and inadequate enumeration and characterization of risks. EIS guidance specifies that hazard scenarios should be "reasonably foreseeable," but the ones used in the USAMRIID EIS required multiple failures, such as human errors (e.g., failure to use O-rings to seal the centrifuge tubes) and safety failures (e.g., inoperable high-efficiency particulate air [HEPA] filter). Results appear to present only peak concentrations, rather than total infectious agent dose, which is the most appropriate measure of per-person risk. The EIS contained no documentation of an individual's risk of infection under the prescribed conditions or any description of the effect of population density and population size on the number of cases expected for any of the pathogens of interest. Furthermore, the scenarios only considered exposures beyond the Fort Detrick fence line, with no consideration of exposure to USAMRIID workers or other people on the base. Despite the committee's estimation that an exceptionally large aerosol release might pose a human health risk, there are no reasonably foreseeable scenarios where such a release could occur.

The EIS does not provide a systematic characterization of exposure risks and consequences associated with the scenarios. Nor does it document the effects of mitigation measures on scenarios or how risks would vary under alternative actions. For example, a systematic review would have identified arthropod escape as an exposure scenario, in addition to those characterized in the EIS of escape of an infected animal, mishaps during biological material shipments, terrorist acts, external acts (such as natural disaster or mechanical failures), spread by an infected worker, and cumulative impacts. Several biological agents likely to be studied at the new USAMRIID facility are transmitted by arthropod vectors (such as fleas, mosquitoes, and ticks), and the vectors may be used in the course of research.

> Consideration of such a scenario in the EIS would have shown that there are significant ecological barriers that make associated relative risks small. Another scenario that was not considered was the threat of an insider with malicious intent. Although such a situation is difficult to predict or quantify, it is clearly of concern to the citizens of Frederick County.
>
> The EIS does not provide scenarios describing potential exposure risks involving pathogens to USAMRIID laboratory personnel, but does cite a brief history of cases of laboratory-acquired infections occurring between 1989 and 2002. Review of these cases illustrates both means of transmission and procedures in place to address identification and treatment of affected laboratory workers. Common risks to workers are needle- or sharps-stick accidents, inadvertent aerosol generation that leads to inhalation or ocular/mucosal exposure, and contact with infected laboratory animals.

National Research Counsel of the National Academies, *Evaluation of the Health and Safety Risks of the New USAMRIID High Containment Facilities at Fort Detrick, Maryland*. Washington: National Academies Press, 2010. 1ER7:4.

Not only does the NAS Report find that the catch-all centrifuge accident was not a reasonable surrogate for an intentional act, it also concludes that the EIS was deficient for not including other reasonable scenarios, including: escape of an infected animal; mishaps during biological material shipments, threat of an insider with malicious intent; external acts (such as natural disaster or mechanical failures); spread by an infected worker; and,

cumulative impacts. *Id*. All of these were similarly relevant factors that were not analyzed in the Livermore Lab BSL-3 FREA. 2ER1.

This report exposes the fact that DOE's analyses and conclusions in the FREA in this case relied on a deficient analysis from an EIS by another agency, as detailed in a comprehensive and objective review by the NAS. The NAS Report further demonstrates that the DOE failed to meaningfully consider all relevant factors in the FREA and that its decision not to consider additional factors was defective. Thus, the district court should have allowed this important study to become part of the record and taken its information into consideration.

IX. CONCLUSION AND RELIEF

Tri-Valley CAREs requests (1) declaratory relief of a finding that DOE violated NEPA and the APA, (2) an order requiring DOE to withdraw the RFONSI while DOE prepares an environmental analysis that complies with the mandatory requirements of NEPA and this Court's prior order, and (3) an injunction against continued operation of the BSL-3 facility pending compliance with NEPA.

As a threshold matter, the selection of the appropriate relief in this case is largely a function of the procedural and informational nature of Tri-Valley CAREs' injuries. *Citizens for Better Forestry v. U.S. Department of*

Agriculture, 341 F.3d 961 (9th Cir. 2003). In *Citizens for Better Forestry*, the Ninth Circuit found that a violation of NEPA's procedural requirements

> is tied to a substantive harm to the environment – the harm consists of added risk to the environment that takes place when governmental decisionmakers make up their minds without having before them an analysis (with public comment) of the likely effects of their decision on the environment. NEPA's object is to minimize that risk, the risk of uninformed choice.

Id. at 971 (internal citations omitted).

In light of the essentially procedural nature of NEPA, Tri-Valley CAREs' NEPA injury can be redressed by a procedural remedy, such as this Court's order to prepare an adequate NEPA analysis. While this Court does have the discretion to enjoin the continued operation of the BSL-3 pending NEPA compliance, this Court need not grant such an injunction to afford Tri-Valley CAREs meaningful and effective relief. Rather, declaratory relief and an order requiring DOE to complete an adequate NEPA analysis will redress Tri-Valley CAREs' injuries. *Id.* at 975-76; see also *Ocean Advocates,* 402 F.3d at 860-61 (NEPA injury is redressed by order to prepare adequate NEPA analysis since decisions can be influenced by that analysis); *Cantrell v. City of Long Beach*, 241 F.3d 674, 682 (9th Cir. 2001) (NEPA injury redressed after completion of adequate NEPA analysis, even if agency ultimately implements the project).

Importantly, in a case like this one – where the facility has been

constructed and is operational – there is still meaningful relief that this Court can provide to vindicate NEPA's core procedural and informational purposes. For example, in *Ocean Advocates* the plaintiffs challenged the NEPA analysis that was prepared by the Army Corps of Engineers in connection with its permit approval of an addition to an oil refinery dock. By the time this Court heard and resolved the plaintiff's appeal, the dock extension was already constructed and was operational. 402 F.3d at 860. Nonetheless, this Court found that "[t]he fact that BP has completed construction of the dock extension does not alter our conclusion, as we can fashion an appropriate remedy." *Id.* at 871. Specifically, this Court found that an adequate NEPA analysis would help to assure that all environmental issues were considered and accounted for in the continued operation of the dock extension:

> If, for example, the Corps determined on remand that the operation of the dock may result in significant degradation of the environment, the Corps could impose restrictions on the operation of the dock or require other mitigating measures. Thus, requiring an EIS would remedy OA's harm.

Id.

Just as in *Ocean Advocates*, this Court may still fashion effective and meaningful relief for Tri-Valley CAREs' NEPA injuries. If this Court were to order DOE to prepare an EIS, or at a minimum, an adequate NEPA analysis, thereby satisfying NEPA's core procedural and informational

purposes, it might well lead DOE to make modifications to and/or implement mitigation measures for its future operations at the BSL-3 to protect human health and environment from a terrorist act.

DOE's failure to candidly define and analyze a bounding event for terrorist attacks results in the loss of a critical opportunity for DOE to demonstrate to itself, Tri-Valley CAREs, the public and this Court that it has comprehensively considered and prepared for such an attack.

Thus, even if this Court decides not to enjoin continued operation of the BSL-3, Tri-Valley CAREs respectfully submits that this Court should issue declaratory relief with an order remanding this matter back to the district court with directions for DOE to prepare an EIS, or in the alternative a compliant NEPA analysis.

Respectfully submitted,

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Dated: March 11, 2011

CERTIFICATE OF COMPLIANCE REGARDING WORD COUNT

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), undersigned counsel for Petitioner hereby certifies that the number of words in Appellants' Opening Brief of March 11, 2011, excluding the Table of Contents, Table of Authorities, Addendum, and corporate disclosure statement, as counted by the Microsoft Word program, is 13,944 words.

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CORPORATE DISCLOSURE STATEMENT OF APPELLANTS' TRI-VALLEY CARES, et al.

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, Appellants Tri-Valley CAREs, et al., submit the following disclosure statement.

Appellants Tri-Valley CAREs, Marylia Kelley, and Janis Kate Turner do not have any parent corporations and do not issue stock. Therefore there is no parent corporation or any publicly held corporation that holds ten percent or more of any appellant's stock for any of these appellants.

Dated: March 11, 2011

Respectfully submitted,

/s/
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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

TRI-VALLEY CARES, MARYLIA KELLEY and JANIS KATE TURNER, Petitioners	)	
v.	)	No. 10-17636
UNITED STATES DEPARTMENT OF ENERGY, NATIONAL NUCLEAR SECURITY ADMINISTRATION and LAWRENCE LIVERMORE NATIONAL LABORATORY, Respondents	)	

CERTIFICATE OF SERVICE

I certify that on March 11, 2011, electronic copies of the foregoing Appellants' Opening Brief were served on the following by posting them on the website for the U.S. Court of Appeals for the Ninth Circuit:

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STATUTORY ADDENDUM

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Statutes

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National Environmental Policy Act

Council on Environmental Quality Regulations

ADMINISTRATIVE PROCEDURE ACT

5 U.S.C. § 702. Right of review

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party. The United States may be named as a defendant in any such action, and a judgment or decree may be entered against the United States: Provided, that any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance. Nothing herein (1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground; or (2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought.

5 U.S.C. § 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be--

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

NATIONAL ENVIRONMENTAL POLICY ACT

42 U.S.C. § 4332. Cooperation of agencies; reports; availability of information; recommendations; international and national coordination of efforts

The Congress authorizes and directs that, to the fullest extent possible: (1) the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in this chapter, and (2) all agencies of the Federal Government shall--

(A) utilize a systematic, interdisciplinary approach which will insure the integrated use of the natural and social sciences and the environmental design arts in planning and in decisionmaking which may have an impact on man's environment;

(B) identify and develop methods and procedures, in consultation with the Council on Environmental Quality established by subchapter II of this chapter, which will insure that presently unquantified environmental amenities and values may be given appropriate consideration in decisionmaking along with economic and technical considerations;

(C) include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on—

(i) the environmental impact of the proposed action,

(ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,

(iii) alternatives to the proposed action,

(iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and

(v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

Prior to making any detailed statement, the responsible Federal official shall consult with and obtain the comments of any Federal agency which has jurisdiction by law or special expertise with respect to any environmental impact involved. Copies of such statement and the comments and views of the appropriate Federal, State, and local agencies, which are authorized to develop and enforce environmental standards, shall be made available to the President, the Council on Environmental Quality and to the public as provided by section 552 of title 5, and shall accompany the proposal through the existing agency review processes.

…

Council on Environmental Quality Regulations

40 C.F.R. § 1502.1 Purpose.

The primary purpose of an environmental impact statement is to serve as an action-forcing device to insure that the policies and goals defined in the Act are infused into the ongoing programs and actions of the Federal Government. It shall provide full and fair discussion of significant environmental impacts and shall inform decisionmakers and the public of the reasonable alternatives which would avoid or minimize adverse impacts or enhance the quality of the human environment. Agencies shall focus on significant environmental issues and alternatives and shall reduce paperwork and the accumulation of extraneous background data. Statements shall be concise, clear, and to the point, and shall be supported by evidence that the agency has made the necessary environmental analyses. An environmental impact statement is more than a disclosure document. It shall be used by Federal officials in conjunction with other relevant material to plan actions and make decisions.

40 C.F.R. § 1502.9 Draft, final, and supplemental statements.

Except for proposals for legislation as provided in Sec. 1506.8 environmental impact statements shall be prepared in two stages and may be supplemented.

…

(c) Agencies:

1. Shall prepare supplements to either draft or final environmental impact statements if:
   (i) The agency makes substantial changes in the proposed action that are relevant to environmental concerns; or
   (ii) There are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts.

…

40 C.F.R. § 1502.22 Incomplete or unavailable information.

When an agency is evaluating reasonably foreseeable significant adverse effects on the human environment in an environmental impact statement and there is incomplete or unavailable information, the agency shall always make clear that such information is lacking.

(a) If the incomplete information relevant to reasonably foreseeable significant adverse impacts is essential to a reasoned choice among alternatives and the overall costs of obtaining it are not exorbitant, the agency shall include the information in the environmental impact statement.

(b) If the information relevant to reasonably foreseeable significant adverse impacts cannot be obtained because the overall costs of obtaining it are exorbitant or the means to obtain it are not known, the agency shall include within the environmental impact statement:

(1) A statement that such information is incomplete or unavailable;
(2) a statement of the relevance of the incomplete or unavailable information to evaluating reasonably foreseeable significant adverse impacts on the human environment;
(3) a summary of existing credible scientific evidence which is relevant to evaluating the reasonably foreseeable significant adverse impacts on the human environment, and

(4) the agency's evaluation of such impacts based upon theoretical approaches or research methods generally accepted in the scientific community. For the purposes of this section, ''reasonably foreseeable'' includes impacts which have catastrophic consequences, even if their probability of occurrence is low, provided that the analysis of the impacts is supported by credible scientific evidence, is not based on pure conjecture, and is within the rule of reason.

…